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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/796,659	03/05/2004	Andrew P. Kramer	GUID.150DIV4	3143

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EXAMINER

EVANISKO, GEORGE ROBERT

ART UNIT	PAPER NUMBER
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3762

DATE MAILED: 07/24/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

<b>Office Action Summary</b>	Application No. 10/796,659	Applicant(s) KRAMER, ANDREW P.	
	Examiner George R. Evanisko	Art Unit 3762	

**-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --**  
**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

#### Status

- 1) ☒ Responsive to communication(s) filed on 15 May 2006.
- 2a) ☐ This action is **FINAL**.                      2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

#### Disposition of Claims

- 4) ☒ Claim(s) 1-44 is/are pending in the application.
- 4a) Of the above claim(s) 3, 4, 9, 10, 14-16, 20, 22, 23, 28, 29, 33-35, 37 and 44 is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1, 2, 5-8, 11-13, 17-19, 21, 24-27, 30-32, 36 and 38-43 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

#### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

#### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All    b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.

#### Attachment(s)

- |  |   |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)  | 4) <input type="checkbox"/> Interview Summary (PTO-413)<br>Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)   | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152)             |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)<br>Paper No(s)/Mail Date <u>6/21/04, 3/5/04</u> . | 6) <input type="checkbox"/> Other: _____  |

## **DETAILED ACTION**

### ***Election/Restrictions***

Claims 3, 4, 9, 10, 14-16, 20, 22, 23, 28, 29, 33-35, 37, and 44 are withdrawn from further consideration pursuant to 37 CFR 1.142(b), as being drawn to nonelected species/inventions, there being no allowable generic or linking claim. Applicant timely traversed the restriction (election) requirement in the reply filed on 5/15/06.

Applicant's election with traverse of the restriction/election in the reply filed on 5/15/06 is acknowledged. The traversal is on the ground(s) that the species are not mutually exclusive, the species overlap in scope, the examiner has not shown the inventions are independent or distinct and the examiner has not shown a serious burden on the examiner. This is not found persuasive because the different species are distinct. According to MPEP 802.01, related inventions are distinct if the inventions as claimed are not connected in at least one of design, operation, or effect (e.g., can be made by, or used in, a materially different process) and wherein at least one invention is PATENTABLE (novel and nonobvious) OVER THE OTHER. Since the species as claimed are distinct (have different operation or effect) restriction is allowed. In addition, although the applicant argues that the species are related, overlap, or are not mutually exclusive, the species may be related and still restricted. According to MPEP 806.04(b) species may be either independent or related under the particular disclosure. Where species under a claimed genus are not connected in any of design, operation, or effect under the disclosure, the species are independent inventions. Where inventions as disclosed and claimed are both (A) species under a claimed genus and (B) related, then the question of restriction must be determined by both the practice applicable to election of species and the practice applicable to

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other types of restrictions such as those covered in MPEP § 806.05 - § 806.05(j). In addition, according to 806.04(f) “[W]here two or more species are claimed, a requirement for restriction to a single species may be proper if the species are mutually exclusive. Claims to different species are mutually exclusive if one claim recites limitations disclosed for a first species but not a second, while a second claim recites limitations disclosed only for the second species and not the first. This may also be expressed by saying that to require restriction between claims limited to species, the claims must not overlap in scope”. Since the claims do not overlap in scope and/or since they recite limitations disclosed for a first species but not a second, and vice versa, the claims are mutually exclusive. Although, the attorney is correct in that disruption of ventricular pacing by an intrinsic ventricular depolarization and disruption by a PVC overlap in scope and therefore the election only between those two species has been withdrawn and the corresponding claims examined. Finally, the argument that the examiner has not shown a serious burden on the examiner is not persuasive. According to MPEP 806.01, a provisional election of a single species may be required where only generic claims are presented and the generic claims recite such a multiplicity of species that an unduly extensive and burdensome search is necessary. Due to the numerous species and that the search is burdensome, extensive, and different for each species, there is a serious burden on the examiner.

The requirement is still deemed proper and is therefore made FINAL.

***Priority***

Applicant's claim for the benefit of a prior-filed application under 35 U.S.C. 119(e) or under 35 U.S.C. 120, 121, or 365(c) is acknowledged. Applicant has not complied with one or more conditions for receiving the benefit of an earlier filing date under 35 U.S.C. [1] as follows:

The later-filed application must be an application for a patent for an invention which is also disclosed in the prior application (the parent or original nonprovisional application or provisional application). The disclosure of the invention in the parent application and in the later-filed application must be sufficient to comply with the requirements of the first paragraph of 35 U.S.C. 112. See *Transco Products, Inc. v. Performance Contracting, Inc.*, 38 F.3d 551, 32 USPQ2d 1077 (Fed. Cir. 1994).

The disclosure of the prior-filed application, Application No. 09/420679, fails to provide adequate support or enablement in the manner provided by the first paragraph of 35 U.S.C. 112 for one or more claims of this application. The prior filed application does not mention "biventricular pacing therapy" and/or a method or apparatus of delivering biventricular pacing therapy using a pacing timing sequence in combination with the other elements and steps, such as providing a PVARP, detecting a disruption, modifying a pacing timing sequence and then delivering biventricular pacing therapy using the modified pacing timing sequence and avoiding PMT during delivery of the biventricular pacing therapy using the modified pacing sequence.

This application repeats a substantial portion of prior Application No. 09/420679, filed 10/19/99, and adds and claims additional disclosure not presented in the prior application. Since this application names an inventor or inventors named in the prior application, it may constitute a

continuation-in-part of the prior application. Should applicant desire to obtain the benefit of the filing date of the prior application, attention is directed to 35 U.S.C. 120 and 37 CFR 1.78. (This paragraph is included since the specification of this application is nearly the same as the specification of the 09/420679 application, but the claim limitations of this application are not described/mentioned in the 09/420679 application. In addition, this application's specification states that it is a division of 09/420679, but 09/420679 had 45 figures and additional pages describing the figures, whereas this application only has 26 figures. It appears this present application repeats the disclosure of 08/833281.)

***Claim Rejections - 35 USC § 112***

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 1, 2, 5-8, 11-13, 17-19, 21, 24-27, 30-32, 36, and 38-43 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the enablement requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention. The subject matter which was not described in the specification is a method or apparatus of delivering "biventricular pacing therapy" and/or a method or apparatus of delivering biventricular pacing therapy in combination with the other elements and steps, such as providing a PVARP, detecting a disruption of the pacing timing sequence, modifying a pacing timing sequence and then delivering biventricular pacing therapy using the modified pacing timing sequence and delivering biventricular pacing therapy using the modified pacing timing

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sequence and avoiding PMT during delivery of the biventricular pacing therapy using the modified pacing sequence.

The original specification describes the use of setting and using PVARPs and AV delays and describes their use with pacing in “a selected ventricle”. Nowhere in the specification, drawings, or abstract is anything remotely mentioned regarding “biventricular pacing therapy” or “delivering the bi-ventricular pacing therapy using a pacing timing sequence”, “detecting a disruption of ventricular pacing”, “modifying the pacing timing sequence”, “delivering the biventricular pacing therapy using the modified pacing timing sequence to promote ventricular pacing” and “delivering biventricular pacing therapy using the modified pacing timing sequence and avoiding PMT during delivery of the biventricular pacing therapy using the modified pacing sequence” in combination with the other elements in the claims (and corresponding structure claims). Although the specification mentions on pages 4, 5, 12, and 18, that the “ventricles” are paced, nowhere is described anything further about pacing the “ventricles” and how the pacing is performed with disruptions and modifications. The specification only provides specific details of a system and method of pacing “a” selected “ventricle” (figure 23).

Due to the lack of an enabling specification for biventricular pacing, several questions arise as to how to make and/or use the invention, such as: How is the biventricular pacing therapy delivered? How does it account for interventricular conduction delays? Is the pacing delivered to both ventricles at the same time or different times? Are one or both ventricles used to deliver the V pulse with the pacing timing sequence? Are one or both ventricles used to initiate the PVARPs? Does the left and right ventricle have different PVARPs? How does the system detect a disruption of ventricular pacing when biventricular pacing is provided? Does the

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system look to both ventricles or the left or right to detect a disruption? Does the system change the amount of modification if the left or right ventricle is paced first? How is the modified pacing timing sequence delivered with the bi-ventricular pacing therapy? Are one or both ventricles used to sense the intrinsic ventricular depolarization? How is PMT avoided during delivery of the biventricular therapy. One example of many showing the necessary detail needed to enable someone skilled in the art how to make and/or use a biventricular pacing therapy system and method is patent number 6496730.

Since there are numerous questions as to how the invention is made and/or used, since no amount of direction or guidance was presented, since other bi-ventricular pacing systems and methods describe in detail how to provide bi-ventricular therapy, and/or since one skilled in the art cannot practice the invention without undue experimentation (as seen by the above questions) because of the number of operational parameters in the process/apparatus that are needed to deliver biventricular therapy, deliver the therapy with the modified timing sequence, and detect a disruption of the ventricular pacing, one skilled in the art to which it pertains is not enabled to make and/or use the invention of the subject matter presented in the claims.

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 1, 2, 5-8, 11-13, 17-19, 21, 24-27, 30-32, 36, and 38-43 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

In claim 1, lines 5 and 6, “ventricular pacing” is vague since it is unclear if this is the same pacing used in line 4 as the biventricular pacing therapy or the pacing timing sequence or if this is a different ventricular pacing.

In claims 11-13, “ventricular pacing” is vague.

In claim 17, In the last line, “is detected” is vague since the claim has not set forth a step to detect a ventricular depolarization.

In claim 18, the claim is not further limiting the parent claim and is vague and conflicts with claim 1 since claim 1 has “biventricular pacing therapy” being delivered, which is inherently to both ventricles, and claim 18 has the therapy being delivered to “one” or more ventricles.

In claims 21 and 36, “ventricular pacing” is vague.

In claim 21, “a pacing timing sequence” is inferentially included and it is unclear if the sequence is being positively recited or functionally recited. In line 9, “a” biventricular pacing therapy is vague since it is unclear if this is the same therapy used in line 6.

In claims 41 and 42, the claims are vague since it is unclear if the means for selecting and the means for pacing are in addition to the means for delivering the biventricular pacing therapy, are the same element, or different elements.


### ***Conclusion***

Any inquiry concerning this communication or earlier communications from the examiner should be directed to George R. Evanisko whose telephone number is 571 272 4945. The examiner can normally be reached on M-F 6:30-5:00.

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If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Angela Sykes can be reached on 571 272 4955. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

  
George R Evanisko  
Primary Examiner  
Art Unit 3762

GRE  
July 18, 2006

7/18/06